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09/919,891	08/02/2001	Brigitte Bathe	211714US0X	5791

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EXAMINER	
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ART UNIT	PAPER NUMBER
1652	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/919,891	Applicant(s) Bathe et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above, claim(s) 10-34 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-9 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the grounds that a search of all the claims would not be a serious burden and that Groups III-VIII are classified in the same class and subclass. This is not found persuasive because as stated in the previous Office Action each of the process of Groups III-VIII are distinct both physically and functionally, have different purposes, and require different process steps, reagents, and parameters.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-9 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequence of SEQ ID NO: 1 and the deduced amino acid sequence of the protein encoded as the amino acid sequence of SEQ ID NO: 2. Applicants disclose that the protein of SEQ ID NO: 2 is a homocysteine methyltransferase which is a generic asserted utility. The specification does not specifically disclose the specific function of the protein of SEQ ID NO: 2 or its relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-9 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the specification does not reasonably provide enablement for any polynucleotide which is at least 70% identical to any polynucleotide which codes for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or any polynucleotide which encodes any polypeptide comprising an amino acid sequence which is 70% identical to the amino acid sequence of SEQ ID NO: 2.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any polynucleotide which is at least 70% identical to any polynucleotide which codes for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or any polynucleotide which encodes any polypeptide comprising an amino acid sequence which is 70% identical to the amino acid sequence of SEQ ID NO: 2. The specification provides guidance and examples for making a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding what amino acids to substitute, delete, or insert into SEQ ID No: 2 in order to make a polypeptide that has at least 70% amino acid identity to SEQ ID NO: 2, the specific biological source of the claimed polypeptide, or the biological function of the claimed polypeptide is lacking. Thus, determining what amino acids to substitute, delete, insert, or combinations thereof into SEQ ID No: 2 in order to make the claimed polypeptide from which a polynucleotide encoding can be made, searching for a biological source that contains the claimed polypeptide, or determining the biological function of the claimed polypeptide is well outside the realm of routine experimentation

and predictability in the art of success is extremely low.

The amount of experimentation to determine what amino acids to substitute, delete, or insert into SEQ ID NO: 2 in order to make a polypeptide that has at least 70% amino acid identity to SEQ ID NO: 2, the biological source of the claimed polypeptide, or the biological function of the claimed polypeptide is enormous. Such experimentation entails selecting the specific amino acids in SEQ ID NO: 2 to substitute, delete, insert, or combinations thereof which would result in a polypeptide that has at least 70% amino acid identity to SEQ ID NO: 2 and determining the biological function of the polypeptide, or screening a vast number of organisms for an organism containing a the claimed polypeptide and determining the biological function of the polypeptide. Since routine experimentation in the art does not include such experimentation, where the expectation of obtaining a polypeptide that has at least 70% amino acid identity to SEQ ID NO: 2 and determining the biological function of the polypeptide is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acids which are to be substituted, deleted, or inserted in SEQ ID NO: 2 and the biological function of the polypeptide. Without such a guidance, the experimentation left to those skilled in the art is undue.

7. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the claimed Eschericha coli strain is required to practice the claimed invention. The Eschericha coli strain must be readily available or obtainable by a repeatable method as set forth in the specification. However, it is not clear that the claimed Eschericha coli strain can be made since the source materials to make the claimed Eschericha coli strain are not both known and readily available to the public. The enablement requirement of 35 U.S.C. § 112 may be satisfied by deposit of the plasmid at a recognized depository.

If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, Applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the

Commissioner upon request;
(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
(4) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 5, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "70% identical to a polynucleotide that codes for a polypeptide which comprises the amino acid sequence of SEQ ID NO: 2" renders the claim vague and indefinite because the specific structure/nucleotide sequence of the polynucleotide which encodes SEQ ID NO: 2 from which the claimed polynucleotide has 70% identity to is not known. Claims 2, 3, and 8 which depends from claim 1 are also rejected because they do not correct the defect of claim 1.

In claim 5 (ii), the phrase "within the range of the degeneration of the genetic code" renders the claim vague and indefinite because the meaning of the phrase is not known.

In claim 5 (iii), the phrase "sense mutations of neutral function" renders the claim vague and indefinite because the meaning of the phrase is not known and the specific nucleotides and the mutations to the specific nucleotides are not known and not recited in the claim.

In claim 5 (iii), the phrase "hybridizes with the sequence complementary" renders the claim vague and indefinite because the specific hybridization conditions are not known and not recited in the claim.

In claim 7, the phrase "metH gene is enhanced" renders the claim vague and indefinite because the specific function and the nucleotide sequence of the metH gene is not known and not recited in the claim and the specific mutation(s) which results in an "enhanced" gene are not known and not recited in the claim. Furthermore, it is not known and not recited in the claim how the claimed gene is "enhanced".

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Eiglmeier et al.

Claim 1 is anticipated by Eiglmeier et al. (Accession AL035310) since Eiglmeier et al. teach a polynucleotide sequence that comprises at least 15 successive/contiguous nucleotides of a polynucleotide encoding SEQ ID NO: 2 (see Alignment No. 1).

12. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Eiglmeier et al.

Claim 5 is anticipated by Eiglmeier et al. (Accession AL035310) since Eiglmeier et al. teach a polynucleotide sequence that encodes a 5-methyltetrahydrofolate-homocysteine methyltransferase, wherein the polynucleotide will hybridize to SEQ ID NO: 1 under low hybridization conditions (see Alignment No. 2).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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